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10/712,629	11/13/2003	Kotikanyadanam Sreekrishna	9423	5723

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THE PROCTER & GAMBLE COMPANY
Global Legal Department - IP
Sycamore Building - 4th Floor
299 East Sixth Street
CINCINNATI, OH 45202

EXAMINER	
DUNSTON, JENNIFER ANN	
ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,629	SREEKRISHNA ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *3-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of an amendment, filed 4/30/2010, in which no claims were amended. Claims 1-8 are pending.

Election/Restrictions

Applicant's election without traverse of Group I and SEQ ID NO: 2 (*Homo sapiens* Ubiquitous Receptor) in the reply filed on 11/16/2004 is acknowledged.

Claims 3-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/16/2004.

Claims 1 and 2 are under consideration as they read on SEQ ID NO: 2.

Specification

The amendment filed 10/20/2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: (i) SEQ ID NOs: 17 and 18; and (ii) the amendment of the paragraph bridging pages 27-28 to recite, "nucleotide position 2915 change from T to C causing a codon change from CCT to CCC) from the published sequence (SEQ ID NO: 18)."

The specification has been amended to define "truncated hairless protein (HRt)" as the sequence provided as SEQ ID NO: 17 (page 5, line 34 to page 6, line 10). Further, the

specification has been amended to indicate that SEQ ID NO: 18 is the nucleic acid sequence encoding amino acids 490 to 1182 of mouse hairless protein (page 7, lines 7-35). The sequence listing has been amended to include new sequences, SEQ ID NOS: 17 and 18, which were not present in the original sequence listing.

The specification indicates that the truncated hairless protein is amino acid residues 490-1182 of the C-terminal portion of mouse hairless (HR) protein (e.g. page 5, line 34 to page 6, line 10). This sequence should be contained in SEQ ID NO: 17. However, a search of the commercial sequence databases using SEQ ID NO: 17 did not identify a single sequence of 100% identity to SEQ ID NO: 17. For example, SEQ ID NO: 17 is 99.4% identical to amino acids 490-1182 of I48378, which is 100% identical to GenBank Accession No. CAA83587 (see the sequence alignments in Appendix I for SEQ ID NO: 17 and I48378, mailed 2/3/2010). There are three mismatches between the protein of instant SEQ ID NO: 17 and the protein of I48378. For clarity, a second alignment comparing the protein encoded by Z32675 and the protein of I48378 is provided (mailed 1/27/2006). This alignment demonstrates that the proteins of I48378 and the protein encoded by Z32675 are 100% identical. An inspection of the sequences provided by Applicant and the sequences known in the art as mouse hairless protein indicates that the sequence provided by Applicant is not amino acid residues 490-1182 of mouse hairless protein.

The specification provides support for the amino acid sequence of mouse hairless protein encoded by GenBank Accession No. Z32675 (e.g. page 7, lines 7-35). However, the sequence provided in the sequence listing is not identical to this sequence. Thus, the amendment is a departure from the specification as originally filed.

The paragraph bridging pages 27-28 describes the location of mutations in mouse HR cDNA obtained by PCR amplification and cloning. The as-filed specification provided nucleotide positions with numbering relative to the fragment amplified, and the amendment filed 10/20/2009 re-numbered the positions relative to the full-length cDNA. For example, position 321 was replaced with position 2165, and position 756 was replaced with position 2600. There's a 1844 nucleotide difference between each of the two numbers. However, position 1076 was replaced with 2915, which is not a 1844 nucleotide difference.

Position 1076 in SEQ ID NO: 18 is not a T. Thus, one would have recognized that the originally filed paragraph contains an error. While there is no in *haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure. An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also recognize the appropriate correction. *In re Oda*, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971). In the instant case, one would have recognized that the reference to position 1076 (or position 1076+1844 = position 2920) was in error, because there is no T at position 1076 to be changed to C. However, one would not have recognized the appropriate correction. For example, another correction could have been position 1077 (or position 1077 + 1844 = position 2921), to identify a T, where a T to C mutation causes a codon change from CCT to CCC.

Response to Arguments - Specification

Applicant's arguments filed 4/30/2010 have been fully considered but they are not persuasive.

With respect to SEQ ID NO: 18, the response asserts that the sequence is disclosed in the Begona reference in Figure 2, which was properly incorporated by reference. The response asserts that the Begona reference is clearly identified on page 27, and the specification coveys an intent to incorporate the reference on pages 27 and 33 of the originally-filed disclosure. The response specifically points to the statement on page 33 that "[a]ll documents cited are, in relevant part, incorporated herein by reference." The response asserts that such an incorporation by reference of Begona into the specification satisfies 37 C.F.R. § 1.57(b)(1) and (2). The response states that there is nothing in Rule 1.57(b) that requires the expression of the intent to incorporate by reference to be positioned immediately following the clear identification of the referenced publication.

These arguments are not found persuasive. The specification does not contain an incorporation by reference of the sequence now presented as SEQ ID NO: 18. The sequence of SEQ ID NO: 18 appears to align perfectly with the sequence disclosed in Figure 2 of The Begona reference (provided in Exhibit A of the reply). The sequence of SEQ ID NO: 18 is not identical to the sequence of GenBank Accession No. Z32675 for the reasons of record. The Begona reference (Cachon-Gonzalez, M. Begona et al. Proceedings of the National Academy of Sciences, USA, Vol. 91, No. 16, pages 7717-7721, August 1994) states, "The sequence reported in this paper has been deposited in the GenBank data base (accession no. Z32675)." See page 7717, bottom right corner. As noted in the Begona reference and by Applicant, the sequence of

Z32675 is the cDNA sequence of the mouse hairless protein, whereas the sequence of Figure 2 is the genomic sequence of the coding region of the mouse hairless protein from different strains. The specification indicates that all "relevant portions" of the cited references are incorporated by reference (page 33). The originally filed specification makes two references to the Begona reference. The first reference is at page 7 and states the following:

> In the context of the present invention, the "bait" protein is a C-terminal portion of hairless protein of mouse (HRt) having amino acid residues 490 to 1182 (provided as SEQ ID NO:16, the nucleic acid sequence encoding amino acids 490 to 1182 is provided 10 as SEQ ID NO:17) "Structure and Expression of the Hairless Gene of Mice," Begona, M., et al., *J. Proc. Natl. Acad. Sci, USA* 91 :7717-7721, 1994) (GenBank accession no. Z32675).

The second reference is at page 27 and states the following:

> Oligonucleotides are designed to PCR-amplify the desired portion of mouse HR cDNA, based on the published sequence for mouse HR "Structure and Expression of the Hairless Gene of Mice," Begona, M., *et al.,* J. *Proc. Natl. Acad. Sci, USA* 91:7717-7721, 1994) (GenBank accession no. Z32675).

In both instances the specification uniquely identifies the sequence of GenBank accession no. Z32675 as the relevant portion of the Begona reference. The sequence of Figure 2, which is not identical to GenBank accession no. Z32675 is not uniquely identified by the specification or indicated as a relevant portion of the Begona reference to be incorporated by reference. Incorporation by reference of relevant portions of a disclosure does not extend to incorporation of all portions of the disclosure. See *Zenon Environmental Inc., v. United States Filter Corp.* 85 USPQ2d 1118 (Fed. Cir. 2007).

With respect to SEQ ID NO: 17, the response asserts that the sequence is disclosed in the Begona reference in Figure 2, which was properly incorporated by reference for the same reasons as applied to SEQ ID NO: 18.

These arguments are not found persuasive for the reasons set forth above with regard to SEQ ID NO: 18. SEQ ID NO: 17 is not identical to the protein encoded by GenBank accession no. Z32675 but appears to be identical to the sequence set forth in Figure 2 of the Begona reference. However, the sequence of Figure 2 of the Begona reference is not effectively incorporated by reference. There was no intent in the originally filed specification to incorporate by reference the sequence of Figure 2 of Begona. The relevant portions of the disclosure of the Begona reference were limited to GenBank accession no. Z32675, which does not contain or encode the sequence of SEQ ID NO: 17.

The response argues that the amended nucleotide positions of 2165, 2600 and 2915 are not new matter. It is noted that the rejection of record does not indicate that the amendment of positions 2165 and 2600 are new matter. The response correctly indicates that the changes from 2166 to 2165 and from 2611 to 2600 are not new matter, because one would have recognized that an error was present and would have known how to correct the error, since no other nearby positions contained the codons to which the original specification referred. With regard to position 2915, the response asserts that the change corrects a typographical error that would have been recognized by those skilled in the art. Specifically, the response asserts that one would recognize the correction to be made, because there is no other CCT near position 2916.

These arguments are not found persuasive. The originally filed specification referred to position 2916 of the published sequence, GenBank accession no. Z32675 of Begona. (originally

filed specification, paragraph bridging pages 27-28). The sequence of GenBank accession no. Z32675 from positions 2911 to 2930 is agcctaggcc taagcatggc (position 2916 is in bold, and the neighboring CCT codons are underlined). One would not have known whether the correction should be to position 2910 or 2916. The position was changed to 2915 in the amendment filed 10/20/2009, and the response argues that one would know that 2915 was correct, because there is no other CCT near position 2916. The response notes that the CCT at 2921 is farther away than the CCT at 2915. This argument is not found persuasive. Position 2916 is flanked by two CCT codons: one at nucleotides 2913-2915 and the other at 2919-2921. Contrary to Applicant's assertion, the codon at 2919-2921 is near position 2916. For example, the change to position 2600 was the addition of 11 nucleotides, so that it is now 2611. The second CCT codon near 2916 falls within this range. One would not know which CCT was the correct codon.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

Claim Rejections - 35 USC §§ 101, 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. This rejection was made in the Office action mailed 2/3/2010 and is reiterated below.

When determining whether the utility of an invention has been described, one determines whether applicant has described a well-established utility. If not, it is determined whether applicant has made an assertion of specific, substantial and credible utility. A credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for use. In contrast to general utility, a specific utility will be specific to the claimed subject matter. A substantial utility defines a real world utility of the invention, and utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world' context use are not substantial utility (see utility guidelines, Federal Register January 5, 2001, Vol. 66, No. 5, pages 1092-1099).

Claim 1 is drawn to a composition comprising a complex comprising a mouse HRt protein and a human Ubiquitous Receptor (UR). Claim 2 limits the human UR to the sequence encoded by SEQ ID NO: 2.

The specification of the instant application discloses that the present invention provides compositions of hairless protein-hairless protein interacting partner complexes (HR-IP) determined by the present inventors using yeast two- hybrid technology. The hairless protein interacting partners provided by the present invention are listed in Table 1 and include the human Ubiquitous Receptor (UR) (e.g., page 3, line 17 to page 4, line 16; page 6, lines 11-26; Example 1; Table 1).

However, the instant specification does not teach any functional characteristics of the

composition comprising a complex comprising a mouse HRt protein and the Ubiquitous Receptor (UR) as the human interacting partner protein. The specification does not disclose the complex in the context of a cell or organism or any methods or working examples that indicate the complex of the instant invention is involved in any activities or diseases states related to hair growth or hair loss. Since significant further research would be required of the skilled artisan to determine how the complex comprising the **mouse** HRt protein and the **human** UR as the interacting partner protein is involved any activity, the asserted utilities are not substantial. In addition, it is not clear how a complex comprising a mouse protein with a human interacting partner can have specific utility for the activities of hair growth or beautification and/or improvement benefits in humans, since the interaction of a mouse protein and human protein will not occur in nature in the human. Since the utility is not presented in mature form and significant further research is required, the utility is not substantial. The specification asserts the following as patentable utilities for the claimed the composition comprising a complex comprising a mouse HRt protein and the UR as the human interacting partner protein:

1) to assay a test compound for agonist or antagonist activity for a composition comprising the complex (e.g., page 3, lines 18-19; page 4, lines 17-25, page 13, line 13 to page 18, line 15; page 31, line 3 to page 33, line 4), where the agonists or antagonists are used to inhibit or increase hair growth on a surface in a subject comprising applying to the surface a growth inhibiting or growth increasing compound having agonist or antagonist activity for a composition for a time sufficient to increase or decrease the amount of hair on the surface (e.g., page 4, lines 26-34; page 8, lines 13-18); and

2) to prepare polyclonal and monoclonal antibodies, antibody fragments, humanized antibodies, single chain antibodies for affinity purification, detection and/or other

functional studies, where the antibodies specifically bind the complex (e.g., page 9, lines 19-25).

Each of these shall be addressed in turn.

1) To assay a test compound for agonist or antagonist activity for a composition comprising the complex. This asserted utility is not specific or substantial. Such assays can be performed with a composition comprising any proteins or with any protein complexes besides a mouse HRt protein. Nothing is disclosed about how the claimed composition comprising the claimed complex is affected by the compounds. Additionally, the specification discloses nothing specific or substantial for the composition comprising a complex comprising a mouse HRt protein and the human UR that can be identified/selected/validated by this method. Since this asserted utility has not been established for the composition comprising complex comprising a mouse HRt protein and the ubiquitous receptor UR as the human interacting partner protein, so that it could be readily used in a real world sense, the asserted utility is not substantial.

Further, the specification does not disclose the tissues or cell types in which the claimed composition comprising the complex comprising a **mouse** HRt protein and the **human** UR is expressed. The specification also discloses nothing about the normal levels of expression and activities of the claimed the complex comprising the mouse HRt protein and the human UR polypeptide in hair follicles or on the skin. The specification does not disclose any disorders associated with hair loss or hair growth associated with the claimed composition comprising the claimed complex. Furthermore it is not known if promoting the interaction of the complex would be desirable for hair growth, or if it is the inhibition of this interaction which would be desired. Significant further experimentation would be required of the skilled artisan to identify subject

and surface affected by hair loss or hair growth. Since this asserted utility has not been established for the claimed the composition comprising complex comprising a mouse HRt protein and the human UR, so that it could be readily used in a real world sense, the asserted utility is not substantial.

2) To make antibodies, or fragments thereof for affinity purification, detection and/or other functional studies. The antibodies will bind to the complex of the mouse HRt protein and the human UR. However, this asserted utility is not specific or substantial. Antibodies can be made to any protein or protein complex. Antibodies to a complex do not have a specific and substantial use if the complex does not have a specific and substantial use. Using the antibodies for further functional studies does not provide a specific and substantial use. Such assays can be performed with any composition. Performing functional studies so that the complex could be used in a real world sense does not provide a substantial utility.

Therefore, the claimed invention does not have specific, substantial utility.

Claims 1 and 2 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. This rejection was made in the Office action mailed 2/3/2010.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**. This rejection was made in the Office action mailed 2/3/2010 and is reiterated below.

The claims are drawn to a composition comprising a mouse HRt protein. The specification states, "By 'truncated hairless protein (HRt)' is meant the sequence provided as SEQ ID NO: 17" (page 5, line 34 to page 6, line 1). However, this is not a limiting definition, because the specification goes not to state that "Derivatives, fragments, or analogs of HR known to one of skill in the art in light of the present disclosure are considered equivalents of HR." (page 6, lines 2-3). At the paragraph bridging pages 27-28, the specification describes the sequence of the HRt protein used in the yeast two-hybrid assay, where the HRt protein is encoded by a nucleic acid sequence obtained from PCR amplification of a cDNA molecule, and where the amplified and cloned nucleic acid sequence contains mutations relative to the prior art sequence of SEQ ID NO: 18. The claims encompass this disclosed variant.

In the amendment filed 10/20/2009, the paragraph bridging pages 27-28 was amended to recite, "nucleotide position 2915 change from T to C causing a codon change from CCT to CCC) from the published sequence (SEQ ID NO: 18)." The reply filed 10/20/2009 asserts that the amendment is supported by counting the nucleotides in the HR gene sequence on page 7719 of the Begona reference, the relevant parts of which were incorporated by reference at page 33, lines 28-29.

The paragraph bridging pages 27-28 describes the location of mutations in mouse HR cDNA obtained by PCR amplification and cloning. The as-filed specification provided nucleotide positions with numbering relative to the fragment amplified, and the amendment filed

10/20/2009 re-numbered the positions relative to the full-length cDNA. For example, position 321 was replaced with position 2165, and position 756 was replaced with position 2600. There's an 1844 nucleotide difference between each of the two numbers. However, position 1076 was replaced with 2915, which is not an 1844 nucleotide difference.

Position 1076 in SEQ ID NO: 18 is not a T. Thus, one would have recognized that the originally filed paragraph contains an error. While there is no in *haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure. An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also recognize the appropriate correction. *In re Oda*, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971). In the instant case, one would have recognized that the reference to position 1076 (or position 1076+1844 = position 2920) was in error, because there is no T at position 1076 to be changed to C. However, one would not have recognized the appropriate correction. For example, another correction could have been position 1077 (or position 1077 + 1844 = position 2921), to identify a T, where a T to C mutation causes a codon change from CCT to CCC.

Furthermore, the specification indicates that the truncated hairless protein is amino acid residues 490-1182 of the C-terminal portion of mouse hairless (HR) protein (e.g. page 5, line 34 to page 6, line 10). This sequence should be contained in SEQ ID NO: 17. However, a search of the commercial sequence databases using SEQ ID NO: 17 did not identify a single sequence of 100% identity to SEQ ID NO: 17. For example, SEQ ID NO: 18 is 99.4% identical to amino acids 490-1182 of I48378, which is 100% identical to GenBank Accession No. CAA83587 (see

the sequence alignments in Appendix I for SEQ ID NO: 17 and I48378, mailed 2/3/2010). There are three mismatches between the protein of instant SEQ ID NO: 17 and the protein of I48378. For clarity, a second alignment comparing the protein encoded by Z32675 and the protein of I48378 is provided (mailed 1/27/2006). This alignment demonstrates that the proteins of I48378 and the protein encoded by Z32675 are 100% identical. An inspection of the sequences provided by Applicant and the sequences known in the art as mouse hairless protein indicates that the sequence provided by Applicant is not amino acid residues 490-1182 of mouse hairless protein.

The specification provides support for the amino acid sequence of mouse hairless protein encoded by GenBank Accession No. Z32675 (e.g. page 7, lines 7-35). However, the sequence provided in the sequence listing is not identical to this sequence. Thus, the amendment is a departure from the specification as originally filed.

The original specification, drawings and claims were thoroughly reviewed and no support could be found for the amendment. Accordingly, the amendment is a departure from the specification and claims as originally filed, and the passages that Applicant has provided do not provide support.

Response to Arguments - USC §§ 101, 112

With respect to the rejection of claims 1 and 2 under 35 U.S.C. 101, because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, Applicant's arguments filed 4/30/2010 have been fully considered but they are not persuasive.

The response asserts that the specific utility of the present invention is to use the HRt-protein-human interacting partner protein complexes, such as HRt-IP complexes that comprise *Homo sapiens* Ubiquitous Receptor, for screening and/or discovery of compounds having agonist or antagonist activity for binding to the hairless protein interacting partner complex. The response asserts that utility finds support in Examples 2 and 3. The response asserts that the identified agonists or antagonists are further tested to determine whether they convey one or more of the following benefits to mammalian skin: improved epidermal barrier function and hydration, cellulite reduction, enhanced barrier repair, prevention, and prevention or reversal of skin wrinkling and hair growth retardation. Thus, the response asserts that the claimed invention is supported by a specific utility, because on would recognize that the asserted utility of the claimed composition is true and useful.

These arguments are not found persuasive. The asserted utility must be specific and substantial. Nothing is disclosed in the present specification about how the claimed composition comprising the complex would be affected by the compounds. It was not known if a compound that promotes the interaction of the mouse HRt-human Ubiquitous Receptor complex would improve epidermal barrier function or reduce epidermal barrier function, for example. The skin of an animal, such as a mouse or human, will not contain the **mouse** HRt-**human** Ubiquitous Receptor complex. Significant further experimentation would be required of the skilled artisan to establish how to use the compounds, since nothing is known regarding the effects of an identified compound on any of epidermal barrier function and hydration, cellulite levels, barrier repair, skin wrinkling, and hair growth retardation. As noted by Applicant further

experimentation would be required to determine any real world uses of the identified compounds. Thus, the asserted utility is not substantial.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

With respect to the rejection of claims 1 and 2 under 35 U.S.C. 112, first paragraph (enablement), Applicant's arguments filed 4/30/2010 have been fully considered but they are not persuasive.

The claims are rejected because one skilled in the art clearly would not know how to use a composition that is not supported by either a specific and substantial asserted utility or a well established utility. The response asserts that the claims are enabled because the claims are supported by a specific utility related to using the claimed complexes for screening and/or discovery of agonist and antagonist compounds adapted to provide material beautification and improved benefits to mammalian skin.

This argument is not found persuasive, because the claims lack a specific and substantial utility for the reasons set forth above.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

With respect to the rejection of claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph (new matter), Applicant's arguments filed 4/30/2010 have been fully considered but they are not persuasive.

The response asserts that the sequence of SEQ ID NO: 17 is not new matter because the sequence is disclosed in Begona, which Applicants assert was properly incorporated by reference

under 37 C.F.R. § 1.57. Further, the response asserts that the amendments to nucleotide positions 2165, 2600 and 2915 do not constitute new matter for the reasons set forth regarding the objection to the specification.

These arguments are not found persuasive for the reasons set forth above with regard to the objection to the specification. Further, the originally filed specification does not demonstrate a clear intent to incorporate the sequence of Figure 2 of the Begona reference. Thus, the addition of SEQ ID NO: 17 incorporates new matter into the claims. Moreover, the amendment of 2916 to 2915 is new matter, because one would not have recognized that the change was the appropriate correction.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

Response to Amendment - Declaration of Koitkanyadanam Sreekrishna

The declaration under 37 CFR 1.132 filed 4/30/2010 is sufficient to overcome the rejection of claim 1 based upon the application of the Sreekrishna et al (US Patent Application Publication No. 2004/0086945 A1) reference under 35 U.S.C. 102(e).

Response to Arguments - 35 USC § 102

Applicant's arguments, see pages 12-13, filed 4/30/2010, with respect to the rejection of claim 1 under 35 U.S.C. 102(e) as being anticipated by Sreekrishna et al (US Patent Application Publication No. 2004/0086945 A1, have been fully considered and are persuasive. The previous rejection of claim 1 has been withdrawn.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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/Jennifer Dunston/
Primary Examiner
Art Unit 1636